FEB 1 4 2001

K003566

A 510(k) Summary of Safety and Effectiveness

Submitter's name:	Smith & Nephew, Inc., Orthopaedic Division
Submitter's address:	1450 Brooks Road, Memphis, TN 38116
Submitter's telephone number:	901-399-6487
Contact person:	David Henley, Clinical/Regulatory Affairs Specialist II
Date summary prepared:	November 17, 2000
Trade or proprietary device name:	Cofield^2 Eccentric and Lateral Offset Humeral Heads
Common or usual name:	Shoulder Joint Prosthesis
Classification name:	21 CFR 888.3660, shoulder joint metal/polymer, semi-constrained cemented prosthesis – Class II

Substantially Equivalent Legally Marketed Devices

- Aequalis™ Shoulder System – Tornier, S.A.
- Bigliani / Flatow™, The Complete Shoulder Solution – Zimmer, Inc.

Device Description

Cofield^2 Eccentric and Lateral Offset Humeral Heads are manufactured from forged cobalt chrome (CoCr) material (ASTM F799) and are designed for use with existing cobalt chrome humeral stem components from the Cofield^2 Total Shoulder System previously cleared from market.

Device Intended Use

The subject humeral head devices will be mated with approved humeral stem components from the Cofield^2 Total Shoulder System previously cleared for market under K955767. Cofield^2 Eccentric and Lateral Offset Humeral Heads are indicated for use as orthopedic implants for the partial or total replacement of the human shoulder joint articulating either directly against the glenoid face or a compatible glenoid component, respectively. Cofield^2 Eccentric and Lateral Offset Humeral Heads are intended for use with bone cement only (cemented fixation) and for single use only. Cofield^2 Eccentric and Lateral Offset Humeral Heads are intended for the following indications:

Proximal Humeral Prosthesis – (1) complex, acute fractures or fracture-dislocations of the humeral head (e.g. trauma – three and four-part injuries in the Neer classification, or head splitting, or head impression fractures); (2) complex, chronic fractures or fracture-dislocations of the humeral head with malunion, non-union of a small osteoporotic head fragment, or chronic dislocation with loss of humeral head cartilage, or large impression fractures; (3) avascular necrosis with intact glenoid cartilage; and (4) selected patients with arthritis who do not have adequate scapular bone to support a glenoid component or must engage in moderately heavy activities.

Total Shoulder Arthroplasty (when used in conjunction with a compatible glenoid component) – severe destruction of the glenohumeral articular surfaces with intractable chronic pain in rheumatoid arthritis, osteoarthritis, traumatic arthritis, cuff tear arthroplasty, ancient septic arthritis, avascular necrosis with secondary glenoid changes, radiation necrosis, and other failed reconstructive

procedures.
The assembled humeral stem component (including either an eccentric or an offset humeral head) may be used alone for hemiarthroplasty or combined with a Cofield^2 Total Shoulder System glenoid component for use in total shoulder arthroplasty.

Technological Characteristics:
Cofield^2 Eccentric and Lateral Offset Humeral Heads are similar to the legally marketed predicate devices listed above. All of these devices are indicated for total shoulder arthroplasty or hemiarthroplasty, are similar in design to the Cofield^2 Eccentric and Lateral Offset Humeral Heads and have the same technological characterisitcs.

Performance Characterisitcs:
Mechanical *humeral head distraction* testing was performed on these devices and met or exceeded acceptable performance. Data indicate that the Cofield^2 Eccentric and Lateral Offset Humeral Heads are substantially equivalent to legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 4 2001

Mr. David Henley
Clinical/regulatory Affairs Specialist
Smith & Nephew, Inc.
1450 Brooks Road
Memphis, Tennessee 38116

Re: K003566
Trade Name: Cofield^2 Eccentric and Lateral Offset Humeral Heads
Regulatory Class: II
Product Code: KWS
Dated: November 17, 2000
Received: November 20, 2000

Dear Mr. Henley:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Premarket Notification
Indications Enclosure

510(k) Number (if known): K003566

Device Name: **Cofield2 Eccentric and Offset Humeral Heads**

Indications for Use:

When used with an appropriate humeral stem from the Cofield^2 Total Shoulder System, **Cofield^2 Eccentric and Offset Humeral Heads** are indicated for use as orthopedic implants for the partial or total replacement of the human shoulder joint articulating either directly against the glenoid face or a compatible glenoid component, respectively. When used with an appropriate humeral stem, **Cofield^2 Eccentric and Offset Humeral Heads** are intended for use with bone cement only (cemented fixation) and for single use only. **Cofield^2 Eccentric and Offset Humeral Heads** are intended for the following indications:

Proximal Humeral Prosthesis – (1) complex, acute fractures or fracture-dislocations of the humeral head (e.g. trauma – three and four-part injuries in the Neer classification, or head splitting, or head impression fractures); (2) complex, chronic fractures or fracture-dislocations of the humeral head with malunion, non-union of a small osteoporotic head fragment, or chronic dislocation with loss of humeral head cartilage, or large impression fractures; (3) avascular necrosis with intact glenoid cartilage; and (4) selected patients with arthritis who do not have adequate scapular bone to support a glenoid component or must engage in moderately heavy activities.

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(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K003566

Prescription Use Yes
(Per 21 CFR 801.109)

OR

Over-the-Counter Use No
(Optional Format 1-2-96)